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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,940

09/27/2006

Feng Xu

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4572

27476

7590

06/20/2008

NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY R338

P.O. BOX 8097

Emeryville, CA 94662-8097

EXAMINER

WILSON, MICHAEL C

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/567,940	<b>Applicant(s)</b> XU, FENG	
	<b>Examiner</b> Michael C. Wilson	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3-21-08&amp;5-5-06</u>  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Claims 1-22 remain pending.

#### ***Election/Restrictions***

Applicant's election without traverse of Group I in the reply filed on 3-21-08 is acknowledged.

Claims 14-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3-21-08.

Claims 1-13 are under consideration.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-8, 10, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Summoto (Int. J. Cancer, 1997, Vol. 73, pg 556-561).

Summoto administered UV irradiated, inactivated tumor cells transfected with a vector encoding GM-CSF to mice (pg 556, last 6 lines; pg 557, col. 1, "in vivo anti-tumor immunity..."). The cells inherently also comprise DNA encoding tumor antigens. GM-CSF is an "immunogen" because it induces an immune

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response. The phrase "immunogen is expressed in vivo by the mammalian cells" is included because "the mammalian cells" lacks antecedent basis, because plasmid DNA encoding GM-CSF is inherently released into cells of the mammal and "expressed" and because DNA encoding tumor antigen is processed and presented in an MHC context by cells of the mammal as evidenced by the immune response against the tumor cells, which is equivalent to "expressed in vivo" as claimed.

Claims 1, 3, 5-8, 10, 12 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Kojima (Human Gene Therapy, May 20, 2003, Vol. 14, pg 715-728).

Kojima administered UV irradiated, inactivated tumor cells transfected with a vector encoding GM-CSF (716, col. 2, "Cell lines"; and pg 717, col. 1, lines 1-2) to mice. The cells inherently also comprise DNA encoding tumor antigens. GM-CSF is an "immunogen" because it induces an immune response. The phrase "immunogen is expressed in vivo by the mammalian cells" is included because "the mammalian cells" lacks antecedent basis, because plasmid DNA encoding GM-CSF is inherently released into cells of the mammal and "expressed" and because DNA encoding tumor antigen is processed and presented in an MHC context by cells of the mammal as evidenced by the immune response against the tumor cells, which is equivalent to "expressed in vivo" as claimed.

Claims 1, 2, 5-9, 12 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Li (J. Allergy Clin. Immunol. July 2003, Vol. 112, pg 159-167).

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Li administered heat killed E. coli comprising a plasmid encoding peanut antigen to mice (pg 160, col. 2, preparation of HKE-MP123), which generated an immune response against the antigen (pg 161, col. 2, "Results").

Claims 1, 5-8, 12 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Xu (Vaccine, 2003, Vol. 21, pg 644-648; available online to the public on Oct. 25, 2002 and published Jan. 2003).

Xu administered attenuated Shigella comprising a plasmid encoding HIV-1 SF2 Gag antigen to mice, which generated an immune response against the antigen (pg 644-645, section 2.1; pg 645-646, section 3.1). The "attenuated" Shigella of Xu are "inactivated" as claimed because they are not able to proliferate in or spread between mammalian cells (pg 645, last 6 lines).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Summoto (Int. J. Cancer, 1997, Vol. 73, pg 556-561), Kojima (Human Gene Therapy, May 20, 2003, Vol. 14, pg 715-728), Li (J. Allergy Clin. Immunol. July 2003, Vol. 112, pg 159-167) or Xu (Vaccine, 2003, Vol. 21, pg 644-648; available online to the public on Oct. 25, 2002 and published Jan. 2003) in view of the applicant acknowledged art at the time of filing.

Summoto, Kojima, Li and Xu each administered inactivated cells comprising DNA encoding an immunogen to a mammal in vivo and obtained an immune response to the immunogen. Summoto and Kojima did not teach inactivating the cells by heat or hydrogen peroxide. Li did not teach inactivating the cells by UV light or hydrogen peroxide. Xu did not teach inactivating the cells by heat, UV light or hydrogen peroxide.

However, applicants acknowledge that methods of inactivating cells were standard in the art at the time of filing (pg 6, lines 17-19).

Thus, it would have been obvious to those of ordinary skill in the art at the time the invention was made to inactivate cells as described by Summoto, Kojima, Li and Xu using methods were standard in the art at the time of filing, such as heat, UV light and hydrogen peroxide, as acknowledged by applicants on pg 6. Those of ordinary skill would have been motivated to inactivate cells using heat, UV light or hydrogen peroxide as necessary to prevent replication of the cells.

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Thus, Applicants' claimed invention as a whole is *prima facie* obvious in the absence of evidence to the contrary.

### **Conclusion**

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/  
Patent Examiner